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10/576,331	07/18/2007	Brian E. Jones	GC819-2-US/B	7214

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EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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07/26/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,331	Applicant(s) JONES ET AL.
	Examiner SHERIDAN SWOPE	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2011.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-43,47-49,54,60,70-73,75-106 and 109-114 is/are pending in the application.
4a) Of the above claim(s) 9-43,48,49,60,77,84-88 and 92 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-7,47,54,70-73,75,76,89-91,93-106 and 110-114 is/are rejected.
7) ☒ Claim(s) 105 and 106 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 18 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>0808;0611;0611</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants' election of Invention I, SEQ ID NO: 8, and cleaning composition in their response of June 16, 2011 is acknowledged. The elected invention is directed to the Micrococcineae serine protease of SEQ ID NO: 8 and cleaning compositions comprising said protease. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction requirement is deemed proper and is therefore made FINAL.

It is acknowledged that Claims 8, 44-46, 50-53, 55-59, 61-69, 74, 107, and 108 have been cancelled and Claims 1, 9-14, 47, 70, and 75-80 have been amended. Claims 1-7, 9-43, 47-49, 54, 60, 70-73, 75-106, and 109-114 are pending. Claims 9, 10, 11-43, 48, 49, 60, 77, 84-88, and 92 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1-7, 47, 54, 70-73, 75, 76, 89-91, 93-106, and 110-114 are hereby examined.

Priority

The priority date granted for Claims 1, 2, 4-7, 47, 54, 70, 72, 73, 75, 76, 89, 90, 110-114 is November 19, 2003, the filing date of US 60/523,609, which disclosed the recited subject matter. The priority date granted for Claims 3, 71, 91-106 is November 19, 2004, the filing date of PCT/US04/39066, which disclosed the recited subject matter.

Title

The title is objected to because it is not descriptive solely of the elected invention.

Drawings-Objections

Figures 3, 4, 21, 25-36, 38, and 39 are objected to because they are not legible.

Figure 18 is objected to because it is informal.

The legend for Figure 24 is objected to because it is numbered "Figure 28".

Sequence Listing-Objections

The sequence listing filed November 5, 2007 is objected because SEQ ID NO: 8 and 18 are identical.

Specification-Objections

It is noted that two, separate specification were filed on April 18, 2006. It is unclear if said two specifications are identical. Applicants are required to identify the specification to be used for any issued patent.

The specification is objected to for containing hyperlinks. USPTO policy does not permit the USPTO, i.e., via an issued patent, to refer to any commercial sites, since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. Hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not to be included in a patent application. (MPEP 608.01) The specification should be carefully checked and all URLs removed.

Claims-Objections

Claims 105 and 106 are objected to for the term "ASP", which should be defined at its first appearance.

Claims 106 is objected to for the phrase "said composition from about 0.01 to about 0.1 weight percent of ASP", which should be corrected to "said composition comprising from about 0.01 to about 0.1 weight percent of ASP".

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Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 1-4, 6, 7, 47, 54, 70-73, 75, 76, 89-91, 93-106, and 110-114 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-3, 22, 24, 26, 27, 29, 31, 33, 35, 37, 39, 40, 51, 52, 54-57, 59-61, 64-69 of US patent 7985569. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-4, 6, 7, 47, 54, 70-73, 75, 76, 89-91, 93-106, and 110-114 herein and Claims 1-3, 22, 24, 26, 27, 29, 31, 33, 35, 37, 39, 40, 51, 52, 54-57, 59-61, 64-69 of US 7985569 are both directed to variants of SEQ ID NO: 8 and detergent compositions therewith. The claims differ in that Claims 1-3, 22, 24, 26, 27, 29, 31, 33, 35, 37, 39, 40, 51, 52, 54-57, 59-61, 64-69 of US 7985569 recite only variants of SEQ ID NO: 8, while Claims 1-4, 6, 7, 47, 54, 70-73, 75, 76, 89-91, 93-106, and 110-114 herein also encompass SEQ ID NO: 8 per se. The

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portion of the specification in US 7985569 that supports the recited proteins includes embodiments that would anticipate Claims 1-4, 6, 7, 47, 54, 70-73, 75, 76, 89-91, 93-106, and 110-114 herein, e.g., variants of SEQ ID NO: 8, which are also the proteins specifically recited in Claims 1-3, 22, 24, 26, 27, 29, 31, 33, 35, 37, 39, 40, 51, 52, 54-57, 59-61, 64-69 of US 7985569. Claims 1-4, 6, 7, 47, 54, 70-73, 75, 76, 89-91, 93-106, and 110-114 herein cannot be considered patentably distinct over Claims 1-3, 22, 24, 26, 27, 29, 31, 33, 35, 37, 39, 40, 51, 52, 54-57, 59-61, 64-69 of US 7985569 when there are specifically recited embodiments (variants of SEQ ID NO: 8 and detergent compositions therewith) that would anticipate Claims 1-4, 6, 7, 47, 54, 70-73, 75, 76, 89-91, 93-106, and 110-114 herein.

Claims 1-4, 6, 7, 47, 54, 70-72, 75, 76, 89-91, 93-106, and 110-114 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-3, 51, 52, 54-57, and 59-69 of US Application 13/162,104. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-4, 6, 7, 47, 54, 70-72, 75, 76, 89-91, 93-106, and 110-114 herein and Claims 1-3, 51, 52, 54-57, and 59-69 of US 13/162,104 are both directed to variants of SEQ ID NO: 8 and detergent compositions therewith. The claims differ in that Claims 1-3, 51, 52, 54-57, and 59-69 of US 13/162,104 recite only variants of SEQ ID NO: 8, while Claims 1-4, 6, 7, 47, 54, 70-72, 75, 76, 89-91, 93-106, and 110-114 herein also encompass SEQ ID NO: 8 per se. The portion of the specification in US 13/162,104 that supports the recited variants includes embodiments that would anticipate Claims 1-4, 6, 7, 47, 54, 70-72, 75, 76, 89-91, 93-106, and 110-114 herein, e.g., SEQ ID NO: 8 and variants thereof, which are proteins also encompassed by Claims 1-3, 51, 52, 54-57, and 59-69 of US 13/162,104. Claims 1-4, 6, 7, 47, 54, 70-72, 75, 76, 89-91, 93-106, and 110-114 herein

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cannot be considered patentably distinct over Claims 1-3, 51, 52, 54-57, and 59-69 of US 13/162,104 when there are specifically recited embodiments (variants of SEQ ID NO: 8) that would anticipate Claims 1-4, 6, 7, 47, 54, 70-72, 75, 76, 89-91, 93-106, and 110-114 herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

With respect to the non-statutory double patenting rejection(s) made in this Office action, note as follows. The use of the terminology “defined in 35 U.S.C. §154 to §156 and §173” in a terminal disclaimer can result in the terminal disclaimer being found improper. To address this, note that a proper terminal disclaimer need only disclaim the patent’s remaining “full statutory term” as defined in 35 U.S.C., without specifying 35 U.S.C. 154 and 173. This is so, because the “full statutory term” inherently is a statutorily defined item. Accordingly, the following language would be deemed acceptable:

The owner*, _____, of _____ percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending **reference** Application Number _____, filed on _____, and as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the **reference** application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said **reference** application, “as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application,” in the event that: any such patent: granted on the pending **reference** application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a

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reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Note: the above language corresponds to PTO/SB/25 (07-09) (reproduced at page 1400-120 in Revision 7 (July 2008) of the 8th edition of the MPEP), but the reference to 35 U.S.C. 154 and 173 has been deleted.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 54, 70-73, 75, 76, 89-106, and 110-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claim 1, the phrase “serine protease...having at least 70% identity with ...SEQ ID NO: 8” renders the claim indefinite. It is unclear whether said phrase means a serine protease having the same cleavage motif specificity as SEQ ID NO: 8 or a serine protease having any substrate specificity. The skilled artisan would not know the metes and bounds of the recited invention. Claims 2-7, 54, 70-73, 75, 76, 89-106, and 110-114, as dependent from Claim 1, are indefinite for the same reason. For purposes of examination, it is assumed that “serine protease...having at least 70% identity with ...SEQ ID NO: 8” means a serine protease having the same substrate specificity as SEQ ID NO: 8.

For Claim 93, 94, 103, and 104, the phrase “adjunct ingredient” renders the claim indefinite. Neither the claims nor the specification provide a definition of what is encompassed by said phrase. The skilled artisan would not know the metes and bounds of the recited invention. Claims 95-98, 105, and 106, as dependent from Claim 93, 94, 103, and/or 104, are indefinite for the same reason.

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For Claim 99, the phrase “acid stable” renders the claim indefinite. It is unclear whether said phrase means stable to any pH below 7.0, below 6.0, below 5.0, below 4.0, below 3.0, below 2.0, or stable to any pH below any other specific acidic pH. The skilled artisan would not know the metes and bounds of the recited invention. Claims 100-106, as dependent from Claim 99, are indefinite for the same reason.

Claims 1-7, 54, 70-73, 75, 76, 89-91, 93-98, 103, 105, 106, and 110-114 are rendered indefinite for improper antecedent usage as follows.

For Claim 1, “the Micrococcineae” lacks antecedent basis. Claims dependent from Claim 1 are indefinite for the same reason.

For Claims 95-98 and 100-103, the phrase “A cleaning composition according to claim...” should be corrected to “The cleaning composition according to claim...”. Claims dependent from Claim 95 or 96 are indefinite for the same reason.

For Claims 105 and 106, the phrase “A composition according to claim...” should be corrected to “The composition according to claim...”. Claims dependent from Claim 105 are indefinite for the same reason.

Any subsequent rejection, based on clarification of the above phrases and terms, will not be considered a new ground for rejection.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Enablement

Claims 1-4, 6, 7, 47, 54, 70-72, 75, 76, 89-91, 93-106, 110-114 are rejected under 35 U.S.C. 112, first paragraph/enablement, because the specification, while being enabling for the protease of SEQ ID NO: 8 and cleaning compositions therewith, does not reasonably provide enablement for (i) any protein having at least 70% identity to SEQ ID NO: 8 or any fragment thereof, (ii) any serine protease produced by any host cell, (iii) any cleaning composition comprising the protein of SEQ ID NO: 8 (or variant) and any competitive inhibitor thereof, (iv) any cleaning composition comprising the protein of SEQ ID NO: 8 (or variant) and any adjunct ingredient, or (v) any active cleaning composition comprising any protein having at least 70% identity to SEQ ID NO: 8 wherein the cleaning composition has a pH of ~3-5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breadth of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

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Claims 1-4, 6, 7, 54, 70-72, 75, 76, 89-91 are so broad as to encompass any protein having at least 70% identity to SEQ ID NO: 8 or any fragment thereof. Claim 47 is so broad as to encompass any serine protease produced by a host cell. Claims 90 and 91 are so broad as to encompass any cleaning composition comprising the protein of SEQ ID NO: 8 (or variant) and any competitive inhibitor. Claims 93, 94, 103, and 104 are so broad as to encompass any cleaning composition comprising the protein of SEQ ID NO: 8 (or variant) and any adjunct ingredient. Claims 95-106 are so broad as to encompass any active cleaning composition comprising any protein having at least 70% identity to SEQ ID NO: 8 wherein the cleaning composition has a pH of ~3-5.

The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins and compositions broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired protease activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of SEQ ID NO: 8.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. Furthermore, the positions within a protein's sequence where amino acid modifications can be

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made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Galye et al, 1993; Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claims 1-4, 6, 7, 54, 70-72, 75, 76, and 89-91, which encompasses all proteases having at least 70% identity to SEQ ID NO: 8 or any fragment thereof. The specification does not support the broad scope of Claim 47, which encompasses all serine proteases produced by a host cell. The specification does not support the broad scope of Claims 90 and 91, which encompasses all competitive inhibitors. The specification does not support the broad scope of Claims 93, 94, 103, and 104, which encompasses all adjunct ingredients. The specification does not support the broad scope of Claims 95-106, which encompasses all active cleaning composition comprising any protease having at least 70% identity to SEQ ID NO: 8 wherein the cleaning composition has a pH of ~3-5.

The specification does not support the broad scope of Claims 1-4, 6, 7, 54, 70-72, 75, 76, and 89-91 because the specification does not establish (A) regions of the protein structure which may be modified without affecting the serine protease activity (B) the general tolerance of the serine protease activity to modification and extent of such tolerance and (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function. The specification does not support the broad scope of Claim 47 because the specification does not establish (D) the structure and function of all serine proteases produced by

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a host cell. The specification does not support the broad scope of Claims 90 and 91 because the specification does not establish (E) the structure of all competitive inhibitors of any serine protease having at least 70% identity to SEQ ID NO: 8. The specification does not support the broad scope of Claims 93, 94, 103, and 104 because the specification does not establish (F) the structure or function of all adjunct ingredients. The specification does not support the broad scope of Claims 95-106 because the specification does not establish (G) the active ingredients in any cleaning composition comprising any protease having at least 70% identity to SEQ ID NO: 8 wherein the cleaning composition has a pH of ~3-5 (note: the protease of SEQ ID NO: 8 is not active below pH 6; Fig 35). The specification provides insufficient guidance as to which of the essentially infinite possible choices encompassed by Claims 1-4, 6, 7, 47, 54, 70-72, 75, 76, 89-91, 93-106, 110-114 is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of proteases with an enormous number of amino acid modifications of the protease of SEQ ID NO: 8 and detergent compositions therewith. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of protease and compositions having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Written Description

Claims 1-4, 6, 7, 54, 70-72, 75, 76, 89-91 are rejected under 35 U.S.C. 112, first paragraph/written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of serine proteases having at least 70% identity to SEQ ID NO: 8 and any fragment thereof. The specification teaches the structure of only a few representative species of such protease. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of having serine protease activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claim 47 is rejected under 35 U.S.C. 112, first paragraph/written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This claim is directed to a genus of serine proteases produced by any host cell. The specification teaches the structure of only a few representative species of such protease. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of having any serine protease activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the

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claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 90 and 91 are rejected under 35 U.S.C. 112, first paragraph/written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. These claims are directed to cleaning compositions comprising a genus of stabilizing inhibitors for any proteinase having at least 70% identity to SEQ ID NO: 8. The specification teaches the structure of only a single representative species of such compositions. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of comprising a stabilizing inhibitor for any proteinase having at least 70% identity to SEQ ID NO: 8. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 93, 94, 103, and 104 are rejected under 35 U.S.C. 112, first paragraph/written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. These claims are directed to cleaning compositions comprising a genus of adjunct ingredients. The specification teaches the structure and function of only a few representative species of such adjunct ingredients. The genus of adjunct ingredients encompassed is a large and variable genus with the potentiality of

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having many different structures and functions. Therefore, many structurally and functionally unrelated agents are encompassed within the scope of these claims. The specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality being an “adjunct ingredient”. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 95-106 are rejected under 35 U.S.C. 112, first paragraph/written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of cleaning compositions comprising any serine protease having at least 70% identity to SEQ ID NO: 8 wherein the cleaning composition has a pH of ~3-5. The specification teaches no representative species of such the cleaning composition and, in fact, teaches that the protease of SEQ ID NO: 8 is not active below pH 6 (Fig 35). Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3 is rejected under 35 U.S.C. 102(e) as being anticipated by Kim et al, 2008 (priority date 18-MAY-2003). Kim et al teaches the protease of SEQ ID NO: 8 (obtained from *Cellulomonas*) and a composition therewith having glycerol [114]. Therefore, Claim 3 is rejected under 35 U.S.C. 102(e) as being anticipated by Kim et al, 2008.

Claim 47 is rejected under 35 U.S.C. 102(b) as being anticipated by van Eekelen et al, 1993. van Eekelen et al teaches a method for producing a serine protease in a *Bacillus* host cell and the produced serine protease (Claim 1 and Fig 1). Therefore, Claim 47 is rejected under 35 U.S.C. 102(b) as being anticipated by van Eekelen et al, 1993.

Claim 54 is rejected under 35 U.S.C. 102(b) as being anticipated by Sigma, Inc (1997). Sigma, Inc teaches and composition comprising the tripeptide Gly-Gly-Arg, which is a portion of SEQ ID NO: 8 (12-14). Therefore, Claim 54 is rejected under 35 U.S.C. 102(b) as being anticipated by Sigma, Inc (1997).

Allowable Subject Matter

No claims are allowable.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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